DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Epitek, Inc.
Werner Hampl
President, RA/QA
4801 West 81st Street, Suite 105
Bloomington, MN 55437

JUL 27 2015

Re: K073507
Trade/Device Name: Anchorage™ Access Kit
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated (Date on orig SE ltr): December 10, 2007
Received (Date on orig SE ltr): December 14, 2007

Dear Werner Hampl,

This letter corrects our substantially equivalent letter of March 5, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073507

Device Name: Anchorage™ Access Kit

Indications for Use:

The Anchorage™ Access Kit facilitates percutaneous access in order to establish a guide through which surgical instruments or devices can be intubated.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073507

K073507

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510(k) Summary
Epitek Anchorage™ Access Kit

APPLICANT:

Epitek, Inc.
4801 W. 81st St., Suite 105
Bloomington, MN 55437 USA

Contact Person: Werner Hampl
Telephone: (952) 230-9886
e-mail: whampl@epitekinc.com
Date Prepared: December 10, 2007

DEVICE:

Proprietary Name: Anchorage Access Kit
Classification: Class II;
21 CFR 876.1500;
Endoscope and accessories;
Product Code: KOG

PREDICATE DEVICE:

The subject device is substantially equivalent (i.e., has the same intended use and technological characteristics) to the USGI Medical Transport™ Endoscopic Access Device (K061216).

DEVICE DESCRIPTION:

The Anchorage Access Kit is a system of components used to gain percutaneous access and provide a conduit for the Anchorage Closure Device (K073096) or other surgical instruments.

INDICATIONS FOR USE:

The Anchorage Access Kit facilitates percutaneous access in order to establish a guide through which surgical instruments or devices can be intubated.

TEST RESULTS:

Results of the in-vitro testing, biocompatibility testing, and conformance to consensus and voluntary standards conducted prior to introduction into commerce demonstrate that the Anchorage Access Kit is substantially equivalent to the specified predicate device.